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July 30, 2018

VIA ELECTRONIC FILING

Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Re: ET Docket No. 13-84
Response to *Ex Parte* Filing of Sensormatic

Dear Secretary Dortch:

The Association for the Advancement of Medical Instrumentation ("AAMI") responds to the *ex parte* presentation that Sensormatic Electronics LLC ("Sensormatic") made on November 16, 2016 in the above-referenced proceeding. AAMI strongly disagrees with several statements made in Sensormatic's *ex parte* presentation, as summarized below.

First, Sensormatic's presentation neglects to mention their participation in several AAMI Cardiac Rhythm Management Device Committee ("CRMD Committee") meetings that included *specific* agenda items to discuss electromagnetic interference from electronic article surveillance ("EAS") systems to cardiovascular implantable electronic devices ("CIEDs"). For example, Mr. Ronald C. Reitan[1] presented results of an assessment of Mr. Fred Colen's patent[2] during the CRMD Committee meeting held on May 3, 2016.[3] Sensormatic was afforded the opportunity to review and comment on draft minutes for this meeting. An excerpt of the approved minutes regarding agenda item 6(d) is included below:

> **d) Report of the ISO 14117 EMC task group - industry-wide summary of the assessment of the concepts of the Fred Colen patent presented by Fred Colen at the May 2015 CRMD meeting. (Ron Reitan, Boston Scientific)**

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[1] Mr. Reitan serves as Co-Chair of AAMI CRMD (PC)/WG02, EMC Test Protocols for Pacemakers, ICDs & CRTs.
[2] Sensormatic's November 16, 2016 presentation references the "Colon Patent, US 5,170,806" on page 14.
[3] *See* attached presentation titled "CIED Manufacturer's position regarding US Patent #5,170,806". This presentation is included as "Agenda item 6(d) attachment" in published minutes for the AAMI CRMD Committee meeting held on May 3, 2016.

> Ron Reitan provided information on the industry investigations into the patent presented by Fred Colen. He noted that the position is an industry consensus position of all 5 device manufacturers and was developed as a one-time courtesy. Mr. Reitan noted that the patent would not provide any benefit and would, actually, provide degraded performance and negative effects on device characteristics. Mr. Reitan also noted that the CIED EMC standard ISO 14117, in compliance with ISO directives, shall not contain requirements for any specific design methodologies and, therefore, further inquiries should be directed to the specific device manufacturers. See Attachment 6d for detailed information on the position.
>
> Fred Colen emphasized that the patent focused on making the device as symmetrical as possible. He acknowledged that there are many different ways to accomplish symmetry and appreciates that modern device design has changed considerably over the many years since patent was created. Mr. Colen suggested that the AAMI group consider developing a "symmetry requirement". Ron Reitan responded that symmetry is a design requirement, not a performance requirement, and highlighted that there are tradeoffs reflected in modern design, which represent clinical needs.
>
> Mitchell Shein thanked Mr. Colen for his passion, but acknowledged that there are many methods to achieve performance and that it has never been within the scope of this committee (or the predicate AAMI PC69) to prescribe design requirements. The goal of the committee is to implement tests which provide expectations of safety and effectiveness.
>
> Olin Giles commented that he was disappointed that he didn't hear anything about the level of performance the patent would impart, but acknowledged that certainly design tradeoffs are a standard consideration for any design.

Mr. Ken Tabor, Mr. Jose Hernandez, and Mr. Olin Giles attended the AAMI CRMD Committee meeting held on May 3, 2016 *and* Sensormatic's meeting with the FCC held on November 16, 2016. However, Sensormatic's presentation to the FCC *does not* acknowledge the assessment of Mr. Colon's patent presented during the AAMI CRMD Committee meeting.[4] In particular, Sensormatic did not share with the FCC any of the concerns documented on pages titled "Manufacturer response: Negative effects if implemented" in AAMI's presentation.[5] Further, the "Possible EMI Performance" postulated by Sensormatic on page 15 of their presentation was not shared with CIED manufacturers for review and comment.

Second, as illustrated on page 11 of AAMI's presentation to the FCC, the sensing passband of CIEDs is based on fundamental physiologic rhythms and their detection.[6] Page 4 of Sensormatic's presentation suggests that near-field inductive technology is the only feasible

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[4]*See supra* note 3.
[5]*See supra* note 3, pages 8-12 (pages 13-17 of this filing).
[6]Ronald C. Reitan (Boston Scientific, Inc., Co-Chair AAMI CRMD/WG02), "Radio Frequency Exposure Considerations for Cardiovascular Implantable Electronic Devices (CIEDs)", Nov. 18, 2014.

option for EAS gates. To the contrary, other EAS manufacturers have chosen to operate at higher frequencies than those chosen by Sensormatic.[7]

Third, Sensormatic's presentation contains statements about the International Commission on Non-Ionizing Radiation Protection ("ICNIRP") that are misleading and inappropriately provocative. Page 5 asserts that ICNIRP Guidelines "Were developed by a small, closed group" and are "Basically a technical paper published in a Journal". The publication "Use of the ICNIRP EMF Guidelines" summarizes the globally-recognized role that ICNIRP plays in establishing guidance[8]:

> International recommendations on health-based guidance to limit exposure requires an assessment of possible adverse health effects using established scientific and medical knowledge. This must be based mainly on the science and should be free of vested interest. ICNIRP, as an independent scientific body comprising all essential scientific disciplines, is qualified to carry out the task of assessing possible adverse health effects, together with WHO. ICNIRP is the formally recognized non-governmental organization in NIR protection for the WHO, the International Labour Organization (ILO), and the European Union (EU) and maintains a close liaison and working relationship with these international bodies as well as IEC and CIE for the optical region and with other bodies engaged in NIR protection. ICNIRP's review process includes Standing Committees and additional experts. The consultation process is extensive and includes IRPA national bodies and other independent scientists and organisations world wide. ICNIRP works in conjunction with the WHO to assess health effects of exposure to NIR, which are published in the WHO Environmental Health Criteria monographs, and uses the results of this assessment to draft health-based exposure guidelines.

Sensormatic's statement "RLs are only provided for measurement ease ... not as a limit" demonstrates a fundamental misunderstanding of limiting values[9]:

> Limiting values are given as basic restrictions and reference levels. Basic restrictions directly relate to established health effects. Appropriate safety factors are included. Reference levels are derived from the basic restrictions for worst-case exposure situations and are in quantities that can be easily measured. They provide levels that can be used to determine compliance with the basic restrictions. By using the system of basic restrictions and derived reference levels, the new ICNIRP guidelines offer flexibility for many exposure situations.
> ....

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[7] *See* FCC ID DO4TR7240R, Checkpoint Systems, Inc. Paragraph 2.1 of the "Test Report" exhibit states "The Evolve Antennas with TR7240 Rev04 are an Electronic Article Surveillance System (EAS). The system detects target tags attached to merchandise. The tags resonate around the frequency of 8.2 MHz. The tags on a purchased article can be deactivated. In this case the tags will not resonate in a defined magnetic field which covers an area 3-feet on either side of the antenna in the 7.0 to 10.0 MHz range and triggers an alarm when an non-deactivated target is detected."

[8] International Commission on Non-Ionizing Radiation Protection, *Use of the ICNIRP EMF Guidelines*, 1999.

[9] *Id.*

> Reference levels are provided for practical exposure assessment purposes, to determine whether the basic restrictions are likely to be exceeded. The reference levels are derived from the basic restrictions by mathematical modelling and extrapolation from the results of laboratory investigations at specific frequencies. They apply for maximum coupling conditions of the field to the exposed person, thereby providing maximum protection. Restrictions are different for workers and the general public. The frequency dependence of the reference field levels is consistent with data on both biological effects and coupling of the fields. ICNIRP recommends the use of the reference levels as general guidance for EMF limits for workers and the general public.

Sensormatic's presentation fails to mention that ICNIRP Guidelines serve as the foundation for the European Union Electromagnetic Fields Directive (2013/35/EU).[10] The Directive states:

> (15) The physical quantities, ELVs and ALs, laid down in this Directive are based on the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and should be considered in accordance with ICNIRP concepts, save where this Directive specifies otherwise.

As these examples illustrate, ICNIRP is a respected international organization and their competency was unfairly characterized by Sensormatic.

Finally, AAMI disagrees with Sensormatic's insinuation that MRI compatible devices provide increased immunity to low-frequency electromagnetic sources (e.g., Sensormatic EAS gates) at levels beyond what is specified in ICNIRP 1998. The attached presentation states[11]:

> CIED manufacturers already have, and continue to make improvements in device EMI immunity in response to the need for MR Conditional approved devices

The purpose of this statement and related sub-bullets is to highlight those improvements made to accommodate 64 MHz electromagnetic fields produced by common 1.5 T scanners. Because of factors described in AAMI's presentation (e.g., "Pacing output circuit is not the only contributor to input impedance asymmetry"[12]) and other electromagnetic considerations, improved electromagnetic compatibility at 64 MHz does not necessarily result in improved immunity to interference with frequencies below 100 kHz.

In sum, Sensormatic did not transparently represent prior interactions with AAMI during the FCC meeting held on November 16, 2016. We hope this filing clarifies the record for a few items contained in Sensormatic's presentation.

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[10] DIRECTIVE 2013/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC.

[11] *See supra* note 3, page 14 (page 19 of this filing).

[12] *See supra* note 3, page 6 (page 11 of this filing).

As stated in our Nov. 18, 2014 presentation to the FCC, we contend:

> In their consideration of the "human environment", the FCC should include those humans who are implanted with CIEDs.[13]

Ultimately, AAMI's primary concern is for patient safety:

> We do not want prospective patients to be discouraged from receiving life-saving CIED therapies because of concerns about the public electromagnetic environment.[14]

Please contact the undersigned with any questions or requests for information.

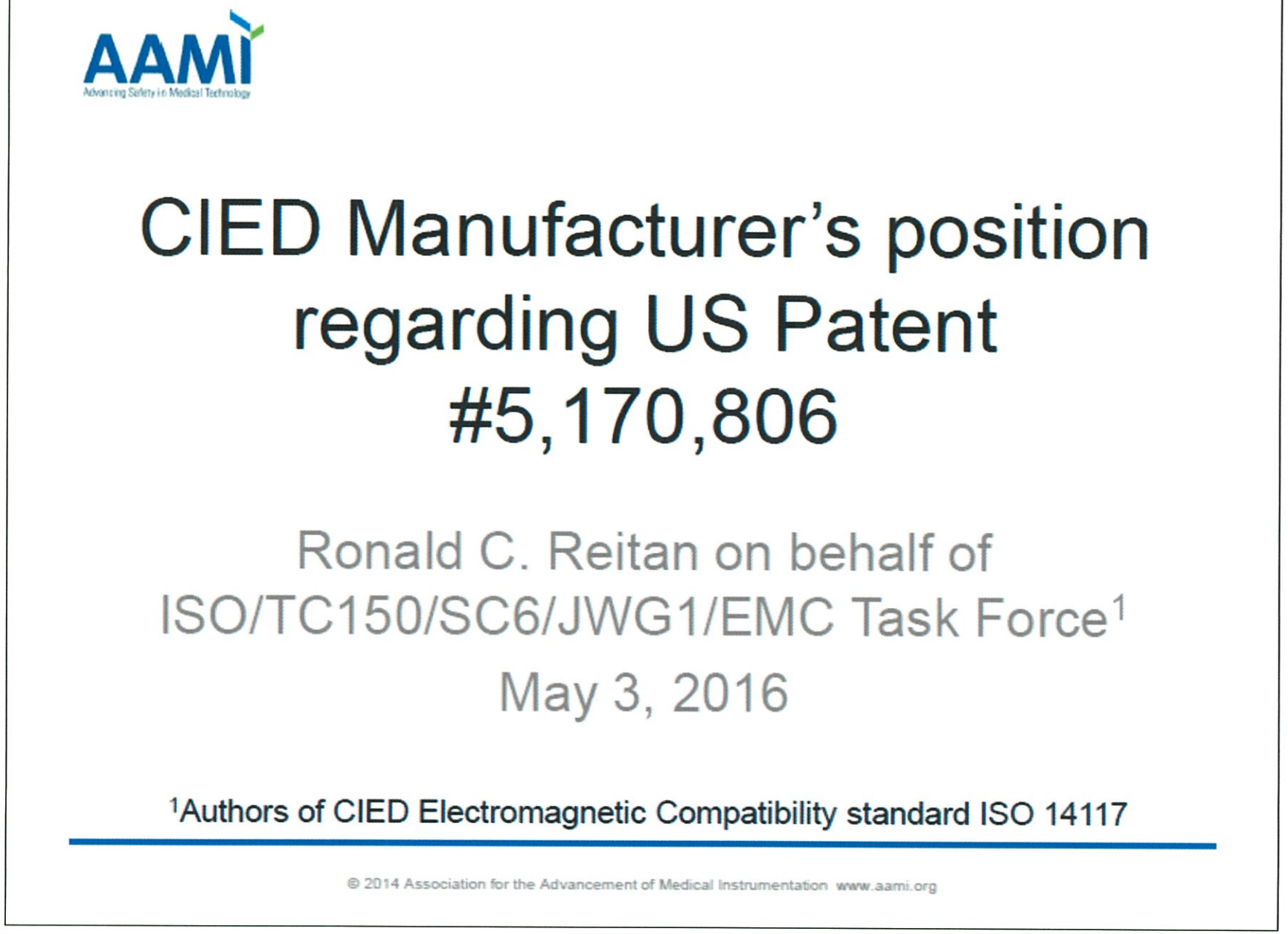
Respectfully submitted,

Robert D. Jensen

Attachment

cc (via email): Julius Knapp
Bruce Romano

[13] *See supra* note 6, page 23.
[14] *See supra* note 6, page 25.


AAMI
Advancing Safety in Medical Technology
CIED Manufacturer's position regarding US Patent #5,170,806
Ronald C. Reitan on behalf of ISO/TC150/SC6/JWG1/EMC Task Force[1]
May 3, 2016
[1]Authors of CIED Electromagnetic Compatibility standard ISO 14117
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Background

- Response provided in support of commitment made to CRMD committee and Sensormatic by the EMC Task Force in November, 2015
- Consensus opinion of all five major CIED manufacturers[1]
- One-time courtesy consideration of US Patent #5,170,806

[1]Biotronik, Boston Scientific, LivaNova, Medtronic, St. Jude Medical

Why a one-time courtesy?

- ISO standards do not prescribe implementation/design methodology, only safety and essential performance. ISO CIED standards (including ISO 14117) are developed with a "performance approach". See ISO/IEC Directives, Part 2, 2011, subclause 4.2:

"Whenever possible, requirements shall be expressed in terms of performance rather than design or descriptive characteristics. This approach leaves maximum freedom to technical development."

- In accordance with these directives, no version of ISO 14117 will require or recommend any specific electrical circuit or EMC architecture approach, including the one recommended by Mr. Colen in the subject patent.

What the patent does

- Adds "decoupling circuit" to isolate pacing output circuit from input stage only during sensing interval

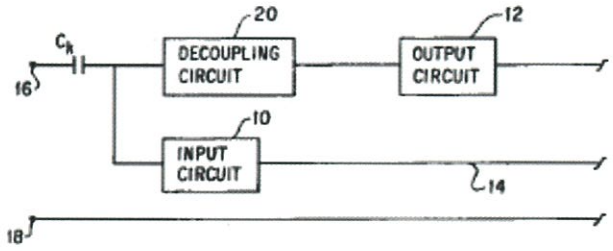


FIG. 1

U.S. Patent Dec. 15, 1992 Sheet 1 of 4 5,170,806

Manufacturer's analysis

- Answering the question:

"Would the technique of this patent significantly improve the EMI immunity of modern CIEDs, especially in the frequency range of 30kHz to 100kHz (where EAS gates manufactured by Sensormatic currently operate)?"

Manufacturer's response: NO

- Pacing output circuit is not the only contributor to input impedance asymmetry
  - ESD protection of sense amp IC inputs
  - Front-end protection from external defib and electrocautery signals
  - Multiplexor circuits ahead of sense amps that allow various sensing vectors to be selected
  - Blocking FETs and diode protection from ICD outputs
  - The patent does not address asymmetry resulting from the electrochemical nature of the body/lead

Consensus opinion of manufacturers

- If we were to test the concept of this patent by taking a MRI-compatible modern device and completely removing the connection to the pacing circuitry (i.e. leaving only the sensing circuit connected to the leads), the immunity of the device to 30 kHz to 100 kHz signals would not be significantly improved from that of an unmodified device.

Manufacturer response: Negative effects if implemented

- Voltage drop in the pacing output path
  - The energy lost in the decoupling circuit can lead to a clinically meaningful reduction in device lifetime, especially in devices providing continuous therapy

Manufacturer response: Negative effects if implemented

- In variable pacing output devices, following a pacing amplitude change, the implementation could require up to 100 pace pulses before steady state is achieved
  - Manual or automated threshold testing nearly impossible without significant patient risk due to loss of capture

Manufacturer response: Negative effects if implemented

- Significantly impacts[1] other critical CIED functions
  - Evoked response detection for capture verification
  - Impedance measurements for determination of chest cavity fluid (HF monitoring)

[1]These functions would be degraded or no longer available in conjunction with the proposed implementation

Manufacturer response: Negative effects if implemented

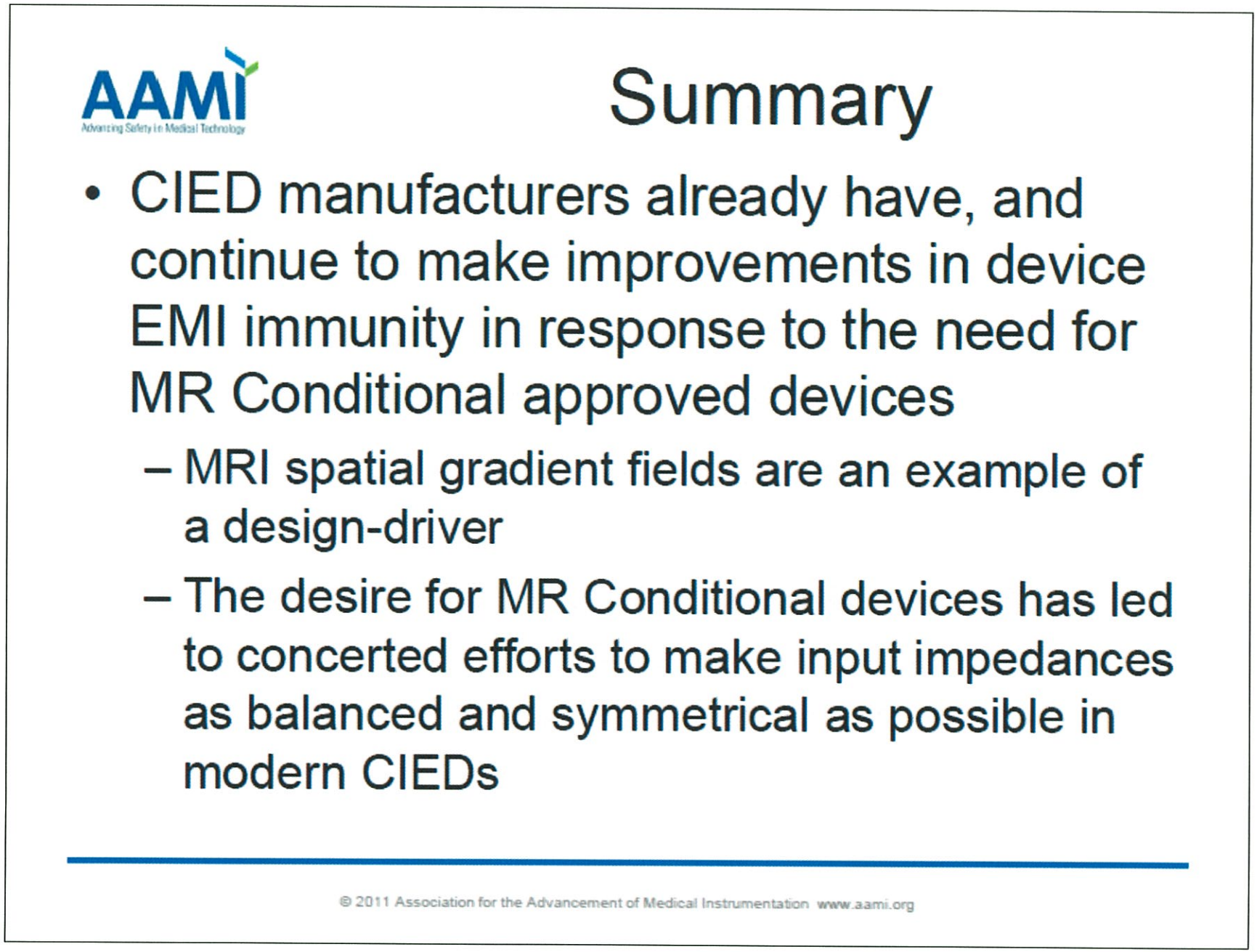
- Increase in device volume, reduced reliability
  - IC/monolithic implementation of the design would reintroduce the same body diode asymmetries that are targeted for avoidance
  - Realistic implementation requires use of many new discrete components requiring more hybrid circuit real-estate
  - Higher discrete component count negatively affects reliability

Manufacturer response: Negative effects if implemented

- Additional severe failure modes
  - The output isolation function introduces a number of new potential failure modes
  - Such failures could lead to a cessation of life-sustaining therapy

Summary

- Implementation of the patent in current-generation devices:
  - Will not provide any additional immunity to EAS systems
  - Accrues multiple negative effects upon performance and device characteristics
    - Increased device size
    - Reduced reliability
    - Reduced longevity
    - Reduced clinical effectiveness
    - Increase in patient safety risk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Summary
• CIED manufacturers already have, and continue to make improvements in device EMI immunity in response to the need for MR Conditional approved devices
– MRI spatial gradient fields are an example of a design-driver
– The desire for MR Conditional devices has led to concerted efforts to make input impedances as balanced and symmetrical as possible in modern CIEDs
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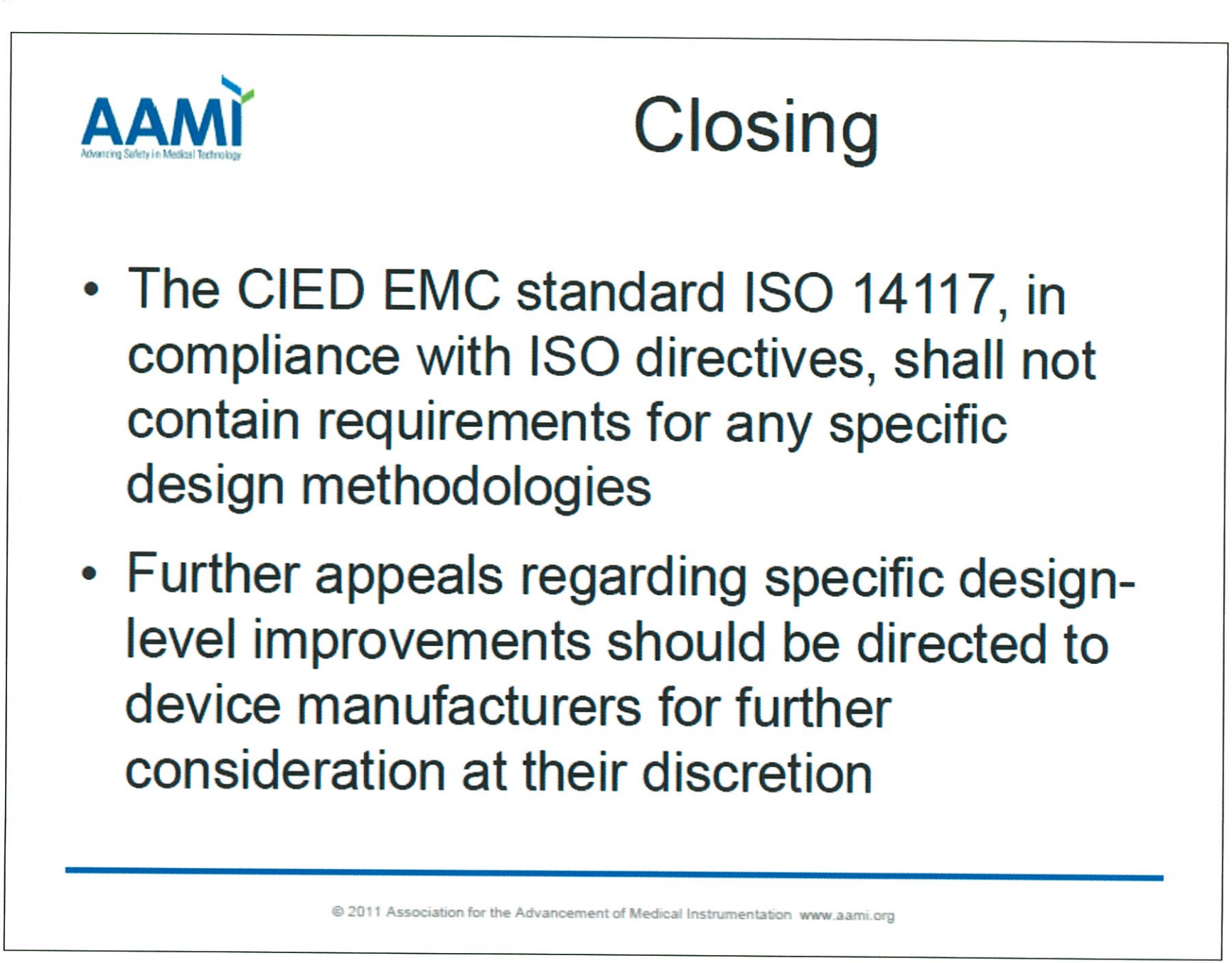
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Closing
• The CIED EMC standard ISO 14117, in compliance with ISO directives, shall not contain requirements for any specific design methodologies
• Further appeals regarding specific design-level improvements should be directed to device manufacturers for further consideration at their discretion
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